IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
JACKSON DIVISION

KAREN M. CROSS **PLAINTIFF**

V. **CIVIL ACTION NO. 3:09-CV-00168-HTW-LRA**

AMTEC MEDICAL, INC., ET AL. **DEFENDANT**

ORDER GRANTING SUMMARY JUDGMENT IN PART AND
DENYING SUMMARY JUDGMENT IN PART

Before the court are four motions for summary judgment. Two motions are by defendants SDI Assets, LLC; SMI Liquidating, Inc. ; Sorenson Medical Products, Inc.; and James Lee Sorenson ("Sorenson defendants") [docket no. 124, 192]; and two motions are by Amtec Medical, Inc. ("Amtec") [docket nos. 136 and 194].

I. JURISDICTION

This court has subject matter jurisdiction over this dispute under diversity of citizenship jurisdiction, Title 28 U.S.C. § 1332.[1] Plaintiff is a citizen of Louisiana. Defendant Amtec Medical, Inc., is a Texas corporation with its principal place of business in Austin, Texas. The Sorenson defendants are Utah Corporations with their principal places of business in Salt Lake City, Utah. Further, the amount in controversy exceeds $75,000 exclusive of costs and interest

[1] Title 28 U.S.C. § 1332 provides:

> The district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between—
> (1) citizens of different States.

II. STANDARD

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23; 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). In response to a motion for summary judgment, the non-moving party must provide specific proof demonstrating a triable issue of fact as to each of the elements required to establish the claim asserted. *Washington v. Armstrong World Indus.*, 839 F.2d 1121, 1122-23 (5th Cir. 1988). The court must resolve all reasonable doubts about the existence of a genuine issue of material fact against the movant. *Byrd v. Roadway Express, Inc.*, 687 F.2d 85, 87 (5th Cir. 1982). Because this matter is before the court by way of diversity jurisdiction, this court will apply the substantive law of the forum state, Mississippi. *Estate of Bradley v. Royal Surplus Lines Ins. Co.*, 647 F.3d 524, 528 (5th Cir. Miss. 2011) (citing *Erie R.R. v. Tompkins*, 304 U.S. 64, 78, 58 S. Ct. 817, 82 L. Ed. 1188 (1938)).

III. FACTS

A. Karen Cross's Surgery

In December of 1999, plaintiff, Karen Cross ("Cross"), then Karen Hamilton, injured her shoulder while working at a tire plant in Ferriday, Louisiana. She Initially sought treatment at Riverland Medical Center in Ferriday, Louisiana, where she was referred to an orthopedic surgeon and underwent physical therapy. In February of 2000, plaintiff first saw orthopedic surgeon Dr. Felix Savoie, M.D. ("Dr. Savoie") at Mississippi Sports Medicine in Jackson, Mississippi. Dr. Savoie recommended that Cross undergo

surgery to repair a torn labrum in her left shoulder. Dr. Savoie explained to Cross that he planned to use a pain pump (possibly the AVIA pain pump produced by defendants) to control her post-operative pain. Cross watched a video in Dr. Savoie's office, which explained how to remove the pain pump after surgery.

On May 31, 2000, Cross underwent a routine arthroscopic surgery at MAE Physician's Surgery Center in Jackson. Following the surgery, Dr. Savoie inserted the catheter of a pain pump into Cross's intra-articular space. The pump was to deliver continuously anesthetic pain medication directly into the operative site for more than 48 hours immediately following the surgery. None of evidence presented by all parties provides a contemporaneous identification of the pain pump brand. The pain pump remained in Cross's shoulder for approximately two days before it was removed. Her worker's compensation record shows a charge of $495.00 to New Alliance of Medical Distributors d/b/a Alliance Medical, dated May 31, 2000.

Cross first reported pain in her shoulder on November 9, 2000, approximately five months after her surgery. Dr. Savoie noted that Cross's "left shoulder was flaring up on her pain wise (sic)," but then noted that he (Dr. Savoie) did not "feel anything and it seemed to be stable." Savoie ordered a magnetic resonance image ("MRI"), which appeared normal. On January 9, 2001, Cross reported "increased pain, [and] decreased range of motion" to her physical therapist, Tom Milliken ("Milliken"). Milliken's assessment, however, indicated that Cross was "progressing towards goals appropriately, [and] will continue with current treatment plan as patient tolerance (sic)." During her visit to Dr. Savoie's office on February 29, 2001, Dr. Savoie noted that "[h]er left shoulder actually looks good[,]" that "[h]er motion is essentially normal[,]" and that

he thought that she was doing well overall. On May 4,2001, Cross reported numbness in her arm and hand, and continued pain in her shoulder. Dr. Savoie noted, however, that "[h]er arm looks quite good[,]" but sent her for a nerve study. The nerve study results came back normal.

On July 6, 2001, Dr. Savoie received a letter from Alliance Medical. Alliance Medical is not a party to this case, but is a third-party service provider for, and is owned by, a group of medical equipment distribution companies, including defendant Amtec. Alliance Medical is responsible for providing billing services and receiving payments related to the AVIA pain pump for Amtec.

The letter states in its pertinent part:

> Karen M. Hamilton's workers compensation company, Alliance General WC, is requesting medical reports/notes. Benefits for this patient cannot be determined without this information, perhaps making the patient liable for entire cost for the use of the AVIA Pain Pump. Forward all info in prepaid envelope.
>
> Thank you for your cooperation in this matter. Any Questions please call 800-862-4446 and ask for Annette Gonzalez or your ***AVIA sales rep Ike Lefleur***. (Emphasis original)

Defendants contend that this letter is unauthenticated hearsay and assert that Gary Brown, President and Chief Operating Officer of Alliance Medical, could not definitively show that an AVIA pump was actually used because the documents have since been destroyed.

On October 11, 2001, Dr. Savoie noted "quite a bit of popping around her shoulder" but again, indicated that "otherwise [she] seems to be doing fine." During this same visit, Dr. Savoie placed Cross at maximum medical improvement without

permanent restrictions or limitations. Dr. Savoie further noted that "I think she'll always have aching in it and discomfort and I think that's related to the fact that she had an injury, surgery, and subsequent recovery and it's not normal or will it ever be normal."

Cross subsequently obtained work, performing various part-time jobs, including one as a waitress. Cross also attended the Louisiana Law Enforcement Training Academy.

Then, on June 13, 2005, Cross saw Dr. Dale Meade ("Dr. Meade") at Sicily Island Medical Center in Sicily Island, Louisiana, for her shoulder pain. Dr. Meade initially suspected tendinitis in the rotator cuff and gave her a steroid injection and a prescription for pain medicine. Cross returned on March 16, 2006 and again on April 18, 2006. During these visits, Dr. Meade noted that Cross's shoulder pain was worsening, that she had decreased range of motion and tenderness, so he prescribed another round of pain medicine.

On April 26, 2006, Cross had an MRI at E.A. Conway Medical Center, located in Monroe, Louisiana. The MRI showed some "osteoarthritic change in the gelenohumeral joint." She was prescribed physical therapy and NSAIDS to treat the symptoms. On May 16, 2006, Dr. Meade diagnosed her shoulder pain as "probably due to arthritis."

On July 11, 2007, another MRI was performed on Cross's shoulder. Cross met with Dr. J.H. Fairbanks ("Dr. Fairbanks") to discuss the MRI results on July 17, 2006. Allegedly, it was at this time that Cross learned that she suffered from Stage IV Degenerative Joint Disease. She had lost cartilage in her shoulder and her bones were touching in the genohumeral joint. This condition would require shoulder fusion or total shoulder replacement. To date, Cross has not yet had a shoulder replacement.

After learning that her shoulder joint had been destroyed, Cross went home and immediately began searching the internet about Stage IV Degenerative Joint Disease. Cross says she discovered that pain pumps, like the one used in her May 31, 2000 surgery, had been associated with loss of cartilage in the shoulder, also called chondrolysis.

Aggrieved over her circumstance, Cross filed suit in this court on March 23, 2009. She submittedthe following claims: (1) product liability for design defect and failure of labeling to warn and (2) negligent manufacture, testing and failure to warn. Cross requests tort damages and punitive damages.

B. AVIA Pain Pump

On January 1, 1999, Sorenson Medical and Amtec Medical entered into an independent distributor agreement where Sorenson would provide its Microject line of pain pumps to Amtec. The agreement gave Amtec the exclusive right to market the Microject pumps in certain states. Using Sorenson's Microject pain pump as the integral component, Amtec assembled a kit along with an introducer needle, an epidural catheter, and a drug reservoir that would be called the AVIA Pain Medication Delivery System. Amtec did not manufacture the Microject pump used in its AVIA kit; it was manufactured by Sorenson.

The Microject pump and the AVIA kit were considered Class II devices by the Food and Drug Administration (FDA). Before marketing a Class II device, a company must submit a 510(k) notification of intent to introduce the product into interstate commerce. Title 21 U.S.C. § 360c(f). The 510(k) must demonstrate that the device is substantially equivalent to a predicate device. Title 21 U.S.C. § 360c(i).

With Sorenson's consent, Amtec submitted a copy of Sorenson's Microject 510(k) application when Amtec submitted its own 510(k) application for the AVIA kit. Amtec was aware at the time of its submission that it was required to show "substantial equivalency" with another device that was already approved. Amtec made no changes to Sorenson's label for the Microject pump.

The FDA places medical devices into three categories. Class I devices are simple products that present minimal potential harm to the user. *See* Title 21 U.S.C. § 360c(a)(1)(A). Class III devices require greater scrutiny before approval because they are intended to support or sustain human life, prevent impairment of human health, or present a potential unreasonable risk of illness or injury to patients. Title 21 U.S.C. § 360c(a)(1)(C)(ii). Class II devices present a greater level of potential risk than Class I devices and may be subject to additional controls, but they do not undergo the same level of scrutiny as Class III devices, nor do they require the same amount of information to be provided. Title 21 U.S.C. § 360c(a)(1)(B).

Amtec's 510(k) application, dated January 22, 1999, stipulated that it was substantially equivalent to products marketed by Sgarlato Labs and I-Flow Corp. The application stated:

> 8.1 The AVIA system is intended to provide continuous infusion of a local anesthetic directly into the intra-operative site for postoperative pain management
>
> 8.2 The AVIA system is intended to deliver pain medication percutaneously via an administration set attached to a catheter.

Amtec's application was accepted on April 22, 1999. The acceptance letter stated that the AVIA Pain Medication Delivery System was "indicated for the relief of pain in

patients following surgery by the continuous administration of medication into the incision site" and that the "system is not intended for intravenous or intra-vascular infusion."

The application and acceptance do not specifically mention whether the AVIA pain pump could be used in the intra-articular joint space. Plaintiff contends that because the intra-articular use is absent from the indications, marketing the pump for intra-articular use was illegal. Further, plaintiff contends that defendants never warned physicians not to use the AVIA pain pump on the intra-articular space.

Defendants contend that intra-articular use was cleared by the FDA through the broad meaning of the sentence "The system is indicated for the relief of pain in patient's following surgery by the continuous administration of medication into the *incision site*" (emphasis added).

IV. ISSUES

A. Statute of Limitations

Amtec has filed a motion for summary judgment [docket no. 136], arguing that the statute of limitations bars plaintiff's claims. Sorenson defendants, join in Amtec's motion [docket no. 146].

The three-year statute of limitations set forth under Mississippi Code § 15-1-49 governs plaintiff's claims. Section 15-1-49 states in pertinent part:

> (1) All actions for which no other period of limitation is prescribed shall be commenced within three (3) years next after the cause of such action accrued, and not after.
>
> (2) In actions for which no other period of limitation is prescribed and which involve latent injury or disease, the

> cause of action does not accrue until the plaintiff has discovered, or by reasonable diligence should have discovered, the injury.

The discovery rule, provided in Section 15-1-49(2), applies to negligence and products liability cases. *Caves v. Yarbrough*, 991 So. 2d 142, 155 (Miss. 2008) (citation omitted); *Williams v. Kilgore*, 618 So. 2d 51, 53 (Miss. 1992). In such cases, the cause of action accrues and the statute of limitations begins at the time "the plaintiff can reasonably be held to have knowledge of the injury itself, the cause of the injury, and the causative relationship between the injury and the conduct . . ." *Smith v. Sanders*, 485 So.2d 1051, 1052 (Miss. 1986). This, however, does not mean that the statute of limitations will toll until the plaintiff is aware that an injury was negligently inflicted. *United States v. Kubrick* 44 U.S. 111, 123; 100 S.Ct. 352; 62 L.Ed.2d 259 (1979). A plaintiff will be held to have sufficient knowledge when he or she has knowledge of both the injury and the cause of that injury. *Smith*, 485 So.2d at 1053.

Plaintiff's surgery was performed on May 31, 2000. Plaintiff filed her complaint on March 23, 2009. Amtec asserts that plaintiff sought medical treatment for pain in her left shoulder as early as November 2000 and continued to seek treatment through 2007. Amtec suggests that upon knowledge that her pain was chronic, plaintiff had enough knowledge for her cause of action to accrue.

Plaintiff explains that the cause of action did not accrue until July 17, 2007 when Dr. Fairbanks diagnosed Cross as having Stage IV Degenerative Joint Disease. It was at that point that she learned that the cartilage in her left shoulder was destroyed, and she would need to undergo a shoulder fusion or a shoulder replacement. After

discovery of her injury, Cross says she researched the condition online, where she discovered the link between her degenerative joint disease and the pain pump. Before the July 17, 2007 diagnosis, Cross says, in accordance with what her doctors told her, she believed that her pain was caused by arthritis and was a normal, permanent result of surgery.

After her surgery, Cross continued seeking medical care through 2007. The record demonstrates that Cross was informed that she was progressing normally after surgery and that her problems were due to arthritis. It was reasonable for her to rely on the doctor's findings. She had no reason to know the difference between pain consistent with normal recovery and abnormal pain due to injury. She had no reasonable basis on which to conclude that her injury may have been caused by the pain pump.

Cross also directs the court to records of doctor visits in 2005 and 2006. During one visit, Dr. Meade stated that Cross's left shoulder pain "[was] probably due to arthritis." Ultimately, Cross underwent an MRI on July 11, 2007, which indicated "extensive arthritic joint space narrowing," among other problems. Cross contends that July 17, 2007, was the first time that she was made aware that her shoulder pain was not due to arthritis.

Amtec, in citing *Wayne General Hospital v. Hayes*, 868 So.2d 997, 1000-01 (Miss. 2004), argues that the tolling of the statute of limitations only occurrs until such time as a plaintiff should have known of some negligent act, even when a plaintiff does not know with absolute certainty that the conduct was legally negligent. Further, the defendants argue that Cross was not required to become absolutely certain that she

had a cause of action. They argue, however, that her chronic pain continuing through the years coupled with her deteriorating condition should have given her sufficient knowledge of facts and thereby gave rise to a duty to inquire as to the cause of her condition.

The jurisprudence here is clear: a plaintiff must not only know, or reasonably should know, that he or she suffers from an injury, but the plaintiff must also know, or reasonably should know, the cause of that injury. This case is distinguishable from the *Wayne General Hospital* case, where signs were present to show the existence of an injury and some negligence on the part of the hospital. In that case, the plaintiff had knowledge that the decedent's death was caused, in part, by sepsis, an infection that does not generally occur in sterile hospital environments without negligence. *Id.* As such, that court held that the statute of limitations was not tolled. *Id.* In this case, the court has not been presented any evidence to show that Cross could have known the nature of her injury or that it might have been caused by the pain pump until April 26, 2006, when she learned of an "osteoarthritic change in the glenohumeral joint;" or July 17, 2006, when she was diagnosed with Stage IV Degenerative Joint Disease and discovered the possible link with the pain pump. Because Cross filed suit on March 23, 2009, both of those dates fall within the three-year statute of limitations period.

Therefore, this court denies Amtec's motion for summary judgment [docket no. 136].

B. Product Identification

The Sorenson defendants have motioned for summary judgment [docket no.

124]. Amtec has joined in that motion [docket no 126]. The Sorenson defendants, relying upon a different argument, motioned for summary judgment on the basis that plaintiff has not submitted sufficient evidence to support her assertion that the Sorenson defendants and Amtec produced the particular pain pump used in plaintiff's 2000 surgery.

Cross has submitted two documents that she claims identify the pump Dr. Savoie inserted in her shoulder after surgery as the defendants' AVIA pain pump. The first is a one page letter sent to Dr. Savoie after Cross's surgery. The letter correctly identifies Cross by her former name (Karen Hamilton) and social security number; correctly identifies her surgeon Dr. Savoie; and correctly identifies the worker's compensation insurer who paid benefits to and on behalf of Cross. The letter goes on to request that Dr. Savoie produce additional information regarding the surgery in order to determine if the patient is "liable for [the] entire cost for the use of the AVIA Pain Pump."

Defendants insist that this letter is hearsay and that the court is barred from considering hearsay documents in summary judgment. *Scales v. Lackey Memorial Hospital*, 988 So.2d 426, 434 (Miss. 2008).This court agrees with the defendants that the letter is hearsay: it is an out-of-court statement that was introduced to prove the truth of the matter asserted. *See* Federal Rules of Evidence Rule 801. This court believes that the letter qualifies under the business record exception[2] to the hearsay

[2]Rule 803(6) of the Federal Rules of Evidence, commonly known as the "Business Record's Exception to the Hearsay Rule states that a record is not hearsay if:

> (A) the record was made at or near the time by–or from information transmitted by–someone with knowledge;
> (B) the record was kept in the course of a regularly conducted activity of business

rule. This letter was written in Alliance Medical's course of business; that is, in the course of seeking payment in its billing operations. Further, even though this letter was written a little over a year after the surgery, it was sufficiently close in time that a billing agency could still be in the course of completing a claim. The letter was also maintained in Dr. Savoie's files as a record of the transaction with Alliance Medical, thus lending trustworthiness to its authenticity. The Fifth Circuit has maintained that letters and reports chronicling an investigation qualify under the business record exception to the hearsay rule. *See Brauninger v. Motes*, 260 Fed. Appx. 2-3 (5th Cir. 2007). Therefore, the letter is admissible and this court will consider it.

The second document is an ledger from Cross's worker's compensation carrier showing a payment of $495.00 to "New Alliance of Independent Medica (sic)" (Alliance Medical), a company owned in part by Amtec for the purpose of managing billings. The Leger shows the payment occurring on the same day as her surgery.

The defendants state that the corporate representative for New Alliance, Gary Brown, testified that the letter was insufficient to show that an AVIA pain pump was used in connection with Cross's post-operative treatment. Plaintiff, however, argues that Brown testified that Amtec, owner of Alliance Medical, was the only company to sell the AVIA pain pump during the relevant time period. Plaintiff also asserts that because Brown testified that he did not handle the paperwork and did not know how the files

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> organization, occupation, or calling, whether or not for profit;
> (C) making the record was a regular practice of that activity;
> (D) all these conditions are shown by the testimony of the custodian or other qualified witness, or by a certification that complies with Rule 902(11) or (12) or with a statute permitting certification; and
> (E) neither the source of information nor the method or circumstances of preparation indicate a lack of trustworthiness.

were kept at Alliance Medical, his opinion as to the letter should not be considered.

A court will grant a motion for summary judgment only if there is "no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c); *see Celotex Corp.*, 477 U.S. at 322-23. This court is persuaded that plaintiff has presented sufficient evidence to raise a genuine issue of material fact as to whether defendants produced the particular pain pump used in her surgery. Therefore, this court denies the Sorenson defendants' motion for summary judgment [docket no. 124].

C. Duty to Warn

Both the Sorenson defendants and Amtec have filed summary judgment motions [docket nos. 192 and 194] arguing that plaintiff's failure to warn claim must fail. These defendants, say plaintiff, have produced no evidence to show that the pain pump labels were inadequate at the time the pump was sold for Cross's surgery.

Defendants further argue that the failure to warn claim must fail because Mississippi has no post-sale duty to warn. The Mississippi Products Liability Act ("MPLA") inflicts liability only for dangers that are known, or that reasonably should have been known, as of the time the product leaves the control of the manufacturer or seller. Miss. Code § 11-1-63(c).[3]

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[3] MPLA 11-1-63(c)(i) state:

> In any action alleging that a product is defective because it failed to contain adequate warnings or instructions pursuant to paragraph (a)(i)2 of this section, the manufacturer or seller shall not be liable if the claimant does not prove by the preponderance of the evidence that at the time the product left the control of the manufacturer or seller, the manufacturer or seller knew or in light of reasonably available knowledge should have known about the danger that caused the damage for which recovery is sought and that the ordinary user or consumer would not realize its dangerous condition.

The defendants assert that the national and statewide medical communities in 2000 were unaware of risks that plaintiff contends existed in relation to the pain pumps. Dr. Savoie, who performed Cross's surgery, was the lead author in an article published in the Journal of Arthroscopy in May-June 2000 studying the effectiveness of using a pain pump to administer pain medication directly into the shoulder after shoulder surgery. The study noted no complications. The defendants say this article is evidence that no risks were known at that time.

Plaintiff does not dispute that Mississippi imposes no post-sale duty to warn. Cross, however, cites numerous studies in existence prior to 2000 that linked joint cartilage toxicity with exposure to foreign substance. Although none of the studies deals directly with the AVIA pump or the medication used with the AVIA pump in Cross' surgery, Cross contends that this research should have made defendants aware of the danger of inserting their product into the fragile intra-articular space.

Plaintiff and defendants have submitted cases from other jurisdictions that have granted[4] and denied[5] summary judgment on cases dealing with pain pumps and injuries like the plaintiff's. Cross has presented evidence in the form of several pre-2000 studies that have linked injections in intra-articular cartilage to joint problems.

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[4] *Rodriguez v. Stryker Corporation*, 2011 WL 31462 (M.D. Tenn. 2011); *Phillippi v. Stryker*, 2010 WL 2650596 (E.D. Cal. 2010); *Meharg v. I-Flow Corp.*, 2010 WL 711317 (S.D. Ind. 2010); *Krumpelbeck v. Breg*, 759 F.Supp.2d 958 (S.D. Ohio 2010) (summary judgment on the inadequate warning claim has recently been reversed and remanded for further proceedings).

[5] *Koch v. Breg, Inc.,* 2010 WL 5301047 (D.S.D. 2010); *Holder v. Breg, Inc.*, Case no. 09-cv-7556 (D. Colo.2010); Smith v. I-Flow Corp, 2011 UlS. Dist. Lexis 47197 (N.D.Ill. 2011); *Monroe v. Zimmer, Inc.*, 766 F.Supp.2d 1012 (E.D.Cal. 2011).

This court is persuaded that the presence of these studies raises a genuine issue of material fact as to whether defendants reasonably should have known at the time of Cross's surgery of the danger their product posed and thereby failed to provide sufficient warning. Therefore, the summary judgment motions on plaintiff's failure to warn claim from the Sorenson defendants [docket no. 192] and Amtec [docket no 194] are denied.

D. Off-Label Use of AVIA Pain Pump

The Sorenson defendants and Amtec have filed summary judgment motions [docket nos. 192 and 194] arguing that plaintiff's claim that the AVIA pain pump was marketed for off-label use must fail because (1) the pain pump was not marketed for off-label use and (2) no private right of action exists for a violation of the Food, Drug and Cosmetics Act (FDCA).

Plaintiff claims that Amtec marketed the AVIA pain pump for use in the intra-articular space, a use that was not specifically approved by the FDA in the 510(k) application. Amtec denies that it marketed the AVIA pain pump for a non-FDA approved use. First, Amtec notes that there is no evidence to substantiate that its marketing representatives ever directed Dr. Savoie, through instruction or literature, to use the AVIA pain pump on the intra-articular space. Further, Amtec points to the FDA 510(k) clearance form, which contained no restrictions. In fact, the FDA approved the pain pump for "the relief of pain in patients following surgery by the continuous administration of medication into the incision site." The defendants insist that, technically speaking, this broad approval could be read to encompass use in the intra-

articular space.

The Sorenson defendants and Amtec assert that even if Amtec marketed the AVIA pain pump for an off-label use, Cross cannot prevail in her claim because the FDCA has provided no private right of action. Medical device manufacturers are prohibited from promoting off-label uses of medical devices. 21 C.F.R. § 801; *see also United States v. Caronia*, 576 F. Supp.2d 385, 389 (E.D.N.Y. 2008). Dissemination of information or instructions regarding a device that are not in compliance with FDA regulations may cause a device to be "misbranded," in violation of the FDCA. 21 U.S.C § 352(n). The FDCA grants the FDA authority to oversee the safety of medical devices, such as the device at issue in this case, and provides that "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a).

Federal courts "have generally interpreted this provision to mean that no private right of action exists to redress alleged violations of the FDCA." *Summit Tech., Inc. v. High-Line Med. Instruments, Co., Inc.,* 922 F. Supp. 299, 305 (C.D. Cal. 1996) (citations omitted, emphasis added). Therefore, even if the defendants marketed the AVIA pain pump for an off-label use, only the FDA or the Department of justice possesses the power to enforce the FDCA. *Id.* This court grant's defendants' motion for summary judgment on the plaintiff's off-label use claim.

V. CONCLUSION

For the reasons cited above, the Sorenson defendants' and Amtec's

Motions for Summary Judgment are granted in part [docket nos. 192 and 194] and denied in part [docket nos. 124, 136, 192, and 194]. This court concludes that the plaintiff is barred from seeking redress for violations of the FDCA because that Act has not provided for a private right of action. This court also concludes that plaintiff has pled sufficiently to raise a genuine issue of fact regarding whether defendants produced the pain pump used in her surgery. Finally, this court concludes that plaintiff's claim is not time-barred by the statute of limitations. Her claim was tolled until such time as she was aware of the injury and the cause of that injury.

SO ORDERED AND ADJUDGED, this the 30th day of September, 2012.

/s/ Henry T. Wingate
UNITED STATES DISTRICT JUDGE

Civil Action No. 3:09-cv-168-HTW-LRA
Order Granting Summary Judgment in Part and Denying Summary Judgment in Part